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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,504	08/07/2003	D. Glenn Purcell	MSE #2675	8474

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,504	PURCELL, D. GLENN	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).

3. Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 3 and 8 of claim 1, the phrase "is adapted to be utilized" is indefinite since the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. See this same problem on line 3 of claim 2, on lines 3 and 5 of claim 8, on lines 5 and 8 of claim 14, on lines 7 and 11 of claim 19, on lines 8 and 14 of claim 28, on lines 7 and 13 of claim 33, on lines 3 and 6-7 of claim 40, and on lines 4 and 6 of claim 44. In addition, see this same problem on line 1 of claim 14 with the phrase "adapted for use", on line 9 of claim 17 with the phrase "adapted to insulate", on lines 2 and 5 of claim 18 with the phrase "adapted to allow", on line 1 of claim 19 with the phrase "adapted for use", on line 1 of claim 27 with the phrase "adapted for use", on lines 1-2 of claim 28 with the phrase "adapted to determine", on line 1 of claim 33 with

the phrase "adapted for use", on line 2 of claim 33 with the phrase "adapted to determine", and on line 2 of claim 41 with the phrase "adapted to be used".

On lines 7 and 11 of claim 19, the phrase "to the sensor" should be changed to –to the one or more sensors—since earlier in the claim, one or more sensors are positively recited.

On line 2 of claim 38, the phrase "the first instrument encoded" should be changed to – the first instrument encoded information—so as to make proper sense.

Claim 40 is indefinite and confusing since it recites that the second encoded calibration information is adapted to be utilized by the first instrument to auto-calibrate the first instrument. However, it is understood from the specification that the inventive concept of the invention is to have first encoded calibration information adapted to be utilized by a first instrument and second encoded calibration information adapted to be utilized by a second instrument.

Claim 42 is indefinite and incomplete since it does not positively recite where the first conductive ink pattern layer is printed. On some type of substrate? In addition, claim 42 does not positively recite where the insulating layer is printed. Over the first conductive layer? In addition, claim 40 does not positively recite where the second conductive ink pattern is printed. Over the insulating layer? Since claim 40 fails to recite where the particular layers are printed in relation to one another, the structure of the auto-calibration label is unclear.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al (US Patent no. 5,856,195, submitted in the Information Disclosure Statement filed on August 7, 2003).

Charlton et al teach of a method and apparatus for calibrating a sensor element used to measure various analytes such as glucose and cholesterol in blood. The sensor element comprises a meter 10 and a sensor package 50 to be inserted into the meter in order for a measurement to take place. The sensor meter 10 has a base member 14 that supports an autocalibration plate 52 and a predetermined number of autocalibration pins 54. The autocalibration pins 54 are connected via a circuit 56 and a connector 58 to associated sensor circuitry in the meter for calibrating the meter. The sensor package 50 carries an autocalibration label 70. Different calibration codes assigned for use in the clinical value determinations to compensate for manufacturing variations between sensor lots are encoded upon the label 70 that is associated with the sensor package 50 of sensors 32. The calibration encoded label 70 is inserted into the instrument with the package 50 of multiple sensors 32, which are stored in individual blisters 33, and read by associated sensor electronic circuitry. Calculation of the correct test values is based upon solving a single equation. Equation constants based on a

calibration code are identified by either using an algorithm to calculate the constants or retrieving the constants from a lookup table for a particular predefined calibration code read from the encoded label 70. The sensor package 50 includes a plurality of fluid sensor cavities or blisters 33 extending toward a peripheral edge of the sensor package 50. Each cavity or blister 33 accommodates one of the plurality of fluid sensors 32. The sensor package is generally circular in shape with the sensor cavities 33 extending from near the outer peripheral edge toward and spaced apart from the center of the sensor package 50. The sensor package includes an autocalibration area 70 providing autocalibration encoded information. This autocalibration encoded information 70 includes a plurality of electrical contact pads 72 aligned for electrical contact with autocalibration pins 54 when the sensor package 50 is received within the sensor meter 10. The autocalibration label 70 includes an inner conductive path or trace 74 and an outer conductive path 76. Selected contact pads 72 are connected to the conductive paths. See lines 18-67 in column 3 and lines 1-38 in column 4 and figures 1-4 in Charlton et al. The autocalibration label 70 is used to automate the process of information transfer about the lot of specific reagent calibration assignment for associated sensors 32. The calibration encoded label is read via the plurality of contacts 72 provided at predetermined positions. Selected ones of the contacts 72 are connected to the outer ring or path 76, other contacts 72 are connected to the inner ring or path 74, and other contacts are not connected. The calibration label is constructed by screen printing conductive ink patterns onto a base substrate. As depicted in Figure 6B of Charlton et al, the autocalibration label 70 includes three sets of contact connections: first contacts 72 (TO, A, D, and E) connected to the outer ring or path 76, second contacts 72 (T1, B, C, F) connected to the inner ring or path 74 and third null contacts or no connection representing

the home position. The label contacts 72 and the inner and outer paths 74, 76 are made of an electrically conductive material. The position of the contacts 72 are aligned with autocalibration pins 54 in the sensor meter to make electrical contact. A predefined calibration encoded pattern consists of the conductive pads 72 interconnected by the conductive rings 74, 76. Calibration data is encoded using selectively electrically interconnected sets of contacts on the label 70. The particular connection pattern of the pads 72 to the inner and outer rings 74, 76 serves to identify the different calibration codes. The calibration codes are used to distinguish between several types of sensors 32. The label code indicates both the sensor type (i.e. glucose, cholesterol, etc) and the calibration code associated with that sensor type. Charlton et al teach that other calibration coded labels 70 can be provided having unique combinations of electrical contacts to the conductive ink patterns and the autocalibration pins in the meter. The different combinations of electrical contacts between the conductive traces and the autocalibration pins indicate different types of calibration codes or labels used to identify one of multiple types of analysis to be performed by the sensor meter 10. See lines 29-57 in column 5, lines 26-44 in column 6, lines 25-53 in column 7, lines 37-50 in column 8 and lines 12-309 in column 9 of Charlton et al.

Therefore, Charlton et al teach of an autocalibration label, a sensor package incorporating the label, and a method for manufacturing the label that comprises first and second encoded calibration information in the form of first and second conductive ink patterns on a substrate that each correspond to a different type of sensor, wherein the encoded information is utilized by a sensor meter in order to auto-calibrate the meter for the particular type and lot of sensor included in the package. However, Charlton et al fail to teach that the first and second encoded calibration information can be used to distinctly calibrate different meter instruments, wherein

one type of meter instrument only recognizes one type of the calibration information on the label. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the autocalibration label taught by Charlton et al encoded data for distinctly and separately calibrating a first type of sensor meter and a second type of sensor meter, wherein each different sensor meter only recognizes one of the distinct calibration codes on the label since Charlton et al teach that the autocalibration label can indicate to a sensor meter one of several different types of analysis to perform based upon the particular type of sensors in the package (i.e. glucose measurement, cholesterol measurement, etc), and one of ordinary skill in the art would recognize that different types of analysis also includes the different types of analyte measurements performed by different sensor meters such as colorimetric or electrochemical measurements. It would have been obvious to one of ordinary skill in the art to calibrate different types of meters that operate differently using the autocalibration label taught by Charlton et al since Charlton et al disclose that the label can include thereon encoded data for performing different types of analysis, and the different types of analysis can include an analysis that matches the parameters for how a particular sensor meter performs to measure an analyte.

Charlton et al also fail to teach that the two conductive ink patterns on the sensor package serving as the encoded calibration information are separated from one another by an insulating layer there between. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to separate the conductive ink patterns used for calibrating separate analysis measurements taught by Charlton et al from one another by an insulating layer so that the first conductive pattern does not electrically interfere with the proper calibration of the second instrument by the second conductive pattern, and the second conductive pattern does

not electrically interfere with the proper calibration of the first instrument by the first conductive pattern.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of several patents by Charlton et al (US Patent nos. 5,854,074, 5,810,199, 5,738,244, 5,630,986 and 5,575,403) that teach of sensor packages containing autocalibration labels therein; and Kawanaka et al (EP 1,024,358) and Hiroshi (JP 2000-19147) who teach of reaction measurement devices including calibration means.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
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mmw

January 5, 2007

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